

**Remarks**

Applicants request reconsideration on the merits of the above-referenced patent application.

**I. Claim amendments**

This amendment cancels claim 50, and adds claims 78-93. Thus, claims 43-49, 51-65, and 67-93 are pending. Claims 43-46, 51, 58-61, 63, 64, and 68-73 have been amended.

Applicants submit that none of the amendments or new claims adds new matter. Specifically:

Claim 43 has been amended to expressly recite the presence of a diluent in the controlled-release formulation. This amendment is supported by Applicants' specification at, for example, page 7, line 24 to page 8, line 4.

The amendments to claims 44-46 and 59-61 simply rephrase the claims to make them easier to read. Applicants submit that such amendments are permissible under MPEP §2163.07.

Claim 51 has been amended to depend from claim 43 rather than canceled claim 50 (which also depended from claim 43).

Claim 58 has been rephrased to more clearly claim the intended subject matter. The amendments are supported by Applicants' specification at, for example, page 4, line 33 to page 5, line 16; page 6, lines 15-17; and page 7, line 2 to page 8, line 4.

Claims 63 and 64 have been amended to remove the "said" characterization of zeranol so that the claims more clearly refer to the *total* amount of zeranol in the composition.

Claims 68-71 have been amended to more clearly reference the controlled-release agent in the dominant claim 58.

Claims 71-73 have been amended to correct the dependencies so that the claims depend from claim 58 rather than claim 43. This corrects an obvious typographical error.

New claims 78-93 correspond to subject matter restricted from examination pursuant to the March 17, 2000 restriction requirement (*i.e.*, original claims 21-42). As noted below, Applicants request that claims 78-93 be rejoined pursuant to MPEP §821.04(b) once claim 43 has been allowed. Because claims 78-93 are not yet rejoined, they are identified as being "withdrawn - new," as required by MPEP §714(II)(C)(E).

Applicants reserve the right to pursue any canceled subject matter and/or any other subject matter disclosed in this application in one or more divisional and/or continuation applications.

## **II. Allowable Subject Matter**

Applicants acknowledge that claims 76 and 77 have been allowed, and the subject matter of claims 44-46, 55, 57, 59-61, and 70 has been found to be allowable. Applicants thank the Examiner for his thorough review of these claims.

## **III. Response to rejection under 35 U.S.C. §102(a)**

Claims 43, 47-54, 56, 58, 62-65, 67-69, and 71-75 have been rejected under 35 U.S.C. §102(a) as being anticipated. Specifically, the Office action indicates that Applicants' specification states that Ralgro is a commercially available formulation that contains *both* immediate- *and* controlled-release zeranol, with lactose as a diluent. In support, the Office action cites to page 9, lines 9-20 of the specification. Applicants request withdrawal of this rejection.

Applicants respectfully submit that the Office action has misquoted Applicants' specification. The relevant cited text is as follows:

Preferably, the anabolic agent useful in the formulation of the present invention is zeranol. A commercially available formulation of zeranol is Ralgro<sup>®</sup> (from Schering-Plough Corporation, Terre Haute, Indiana) which additionally contains some lactose. The zeranol content in the present formulation is in an amount of from about 50 wt.% to 95 wt.% preferably from about 55 wt.% to about 85 wt.% and most preferably from about 60 wt.% to about 80 wt.%, based on the total weight of the implant composition (including both the immediate-release part and the controlled-release part). Page 9, lines 9-17.

**This text does not state that Ralgro contains *both* immediate *and* controlled release zeranol. To the contrary, it states that Ralgro is a formulation of *only* zeranol and lactose. The discussion in the third sentence relating to immediate-release and controlled-release describes Applicants' compositions of this invention --- not Ralgro alone.**

Simply put, Ralgro alone is only zeranol and lactose. It is, therefore, an immediate-release formulation, and does not include a controlled-release formulation. The compositions in

claims 43, 47-54, 56, 58, 62-65, 67-69, and 71-75, in contrast, comprise *both* an immediate-release formulation *and* a controlled-release formulation. Accordingly, Applicants respectfully submit that the claims are novel, and the rejection should be withdrawn.

**IV. Response to objection of claims 44-46, 55, 57, 59-61, and 70 for depending from a rejected base claim**

An objection has been raised to claims 44-46, 55, 57, 59-61, and 70 for depending from a rejected base claim. As indicated above, the rejection of the base claims should be withdrawn. Accordingly, Applicants respectfully request withdrawal of this objection.

**V. Request for rejoinder of withdrawn claims**

New claims 78-93 correspond to subject matter restricted from examination pursuant to the March 17, 2000 restriction requirement. These claims are directed to methods of using compositions falling within the scope of claim 43. Accordingly, Applicants request that claims 78-93 be rejoined pursuant to MPEP §821.04(b), which provides for such rejoinder as a matter of right once composition claims of equal or greater breadth (*e.g.*, claim 43) have been allowed.

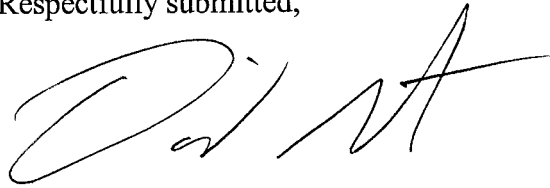
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Applicants hereby request a two-month extension to respond to the July 25, 2007 Office action, and authorize the Commissioner to charge Deposit Account No. **02-2334** for the corresponding extension fee. Applicants do not believe that any other fee is due in connection with this filing. If, however, Applicants do owe any such fee(s), the Commissioner is hereby authorized to charge the fee(s) to Deposit Account No. **02-2334**. In addition, if there is ever any other fee deficiency or overpayment under 37 C.F.R. §1.16 or 1.17 in connection with this patent application, the Commissioner is hereby authorized to charge such deficiency or overpayment to Deposit Account No. **02-2334**.

Applicants submit that the pending claims are in condition for allowance, and request that this application be allowed. The Examiner is requested to call the Undersigned if any issues arise that can be addressed over the phone to expedite examination of this application.

Amendment in Response to July 25, 2007 Office Action  
Appl. No. 09/431,519  
December 26, 2007

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'D. Gryte', with a long horizontal stroke extending to the right.

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